HPTN 096
Integrating Multi-Level Strategies to Reduce HIV Transmission Among Black MSM in the Southern US

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The HIV Epidemic in Black MSM and the Southern US: Prevalence

At the end of 2018, an estimated 1.2 MILLION AMERICANS had HIV. Of those, 235,100 were Black/African American gay and bisexual men.

P. Sullivan et al. Epidemiology of HIV in the USA: epidemic burden, inequities, contexts, and responses. Lancet. Published online February 19, 2021

CDC Fact Sheet, HIV and African American Gay and Bisexual Men, October 2020
The HIV Epidemic in Black MSM and the Southern US: Diagnoses and Incidence

Of the 37,968 NEW HIV DIAGNOSES in the US and dependent areas in 2018, 51% were in the South.

Of the 37,968 NEW HIV DIAGNOSES in the US and dependent areas in 2018, 26% were among Black/African American gay and bisexual men.

Estimated HIV Incidence among Men Who Have Sex with Men Aged ≥13 Years by Race/Ethnicity, 2010-2018—United States

P. Sullivan et al. Epidemiology of HIV in the USA: epidemic burden, inequities, contexts, and responses. Lancet. Published online February 19, 2021

CDC Fact Sheet, HIV in the United States by Region, June 2020

CDC Fact Sheet, HIV and African American Gay and Bisexual Men, October 2020

The HIV Epidemic in Black MSM and the Southern US: Diagnoses

Blacks/African Americans in the South had the highest number of HIV diagnoses compared to other regions.
Efficacious Biomedical Interventions

Social Determinants of Health - Barriers to Testing, PrEP and ART

HIV Testing + PrEP Uptake and Adherence + ART Uptake and Adherence = HIV Transmission

Black MSM
Implementation Framework
Implementation Framework
Implementation Framework

HIV PREVENTION EFFICACY

CLINICAL INTERVENTIONS
Implementation Framework

HIV PREVENTION EFFICACY

CLINICAL INTERVENTIONS

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  (includes all current FDA-approved products)
Implementation Framework

CLINICAL INTERVENTIONS

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  *(includes all current FDA-approved products)*
Implementation Framework

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  *(includes all current FDA-approved products)*

HIV PREVENTION EFFICACY

HIV PREVENTION IMPACT

CLINICAL OUTCOMES
# Implementation Framework

## Clinical Interventions

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  - (includes all current FDA-approved products)

## Clinical Outcomes

- Decrease HIV Transmission
CLINICAL OUTCOMES

▪ HIV Testing
▪ HIV Pre-Exposure Prophylaxis
▪ HIV Treatment
  (includes all current FDA-approved products)

CLINICAL INTERVENTIONS

HIV PREVENTION EFFICACY

HIV PREVENTION IMPACT

▪ Decrease HIV Transmission
Implementation Framework

**HIV PREVENTION EFFICACY**

**CLINICAL INTERVENTIONS**
- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  (includes all current FDA-approved products)

**HIV PREVENTION IMPACT**

**CLINICAL OUTCOMES**
- Decrease HIV Transmission
Implementation Framework

HIV PREVENTION EFFICACY

CLINICAL INTERVENTIONS

▪ HIV Testing
▪ HIV Pre-Exposure Prophylaxis
▪ HIV Treatment
  (includes all current FDA-approved products)

IMPLEMENTATION SCIENCE

HIV PREVENTION IMPACT

CLINICAL OUTCOMES

▪ Increase HIV Detection
▪ Decrease HIV Transmission
Implementation Framework

**HIV PREVENTION EFFICACY**

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  
  (includes all current FDA-approved products)

**HIV PREVENTION IMPACT**

- HIV Viral Suppression
- HIV PrEP Uptake

**IMPLEMENTATION SCIENCE**

**CLINICAL OUTCOMES**
CLINICAL OUTCOMES

▪ HIV Testing
▪ HIV Pre-Exposure Prophylaxis
▪ HIV Treatment
  (includes all current FDA-approved products)

IMPLEMENTATION SCIENCE

HIV PREVENTION EFFICACY

HIV PREVENTION IMPACT

▪ HIV Viral Suppression
▪ HIV PrEP Uptake

DETERMINANTS
Implementation Framework

HIV PREVENTION EFFICACY

CLINICAL INTERVENTIONS

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  \(\text{(includes all current FDA-approved products)}\)

IMPLEMENTATION SCIENCE

HIV PREVENTION IMPACT

CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake

DETERMINANTS
HIV PREVENTION EFFICACY

CLINICAL INTERVENTIONS

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  (includes all current FDA-approved products)

HIV PREVENTION IMPACT

CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake

IMPLEMENTATION SCIENCE

- Intersectional Stigma

DETERMINANTS
Implementation Framework

HIV PREVENTION EFFICACY

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  (includes all current FDA-approved products)

IMPLEMENTATION SCIENCE

- Intersectional Stigma
  - Community-level

DETERMINANTS

HIV PREVENTION IMPACT

- HIV Viral Suppression
- HIV PrEP Uptake

CLINICAL OUTCOMES

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  (includes all current FDA-approved products)
Implementation Framework

HIV PREVENTION EFFICACY

CLINICAL INTERVENTIONS

- HIV Testing
- HIV Pre-Exposure Prophylaxis
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  *(includes all current FDA-approved products)*

HIV PREVENTION IMPACT

CLINICAL OUTCOMES

- HIV Viral Suppression
- HIV PrEP Uptake

IMPLEMENTATION SCIENCE

- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level

DETERMINANTS
Implementation Framework

HIV PREVENTION EFFICACY

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  (includes all current FDA-approved products)

IMPLEMENTATION SCIENCE

- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level
- Culturally non-responsive services

HIV PREVENTION IMPACT

- HIV Viral Suppression
- HIV PrEP Uptake

CLINICAL OUTCOMES

- CLINICAL INTERVENTIONS
HIV PREVENTION EFFICACY

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment (includes all current FDA-approved products)

IMPLEMENTATION SCIENCE

- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level
- Culturally non-responsive services
- Structural barriers to social support

DETERMINANTS

HIV PREVENTION IMPACT

- HIV Viral Suppression
- HIV PrEP Uptake

CLINICAL OUTCOMES

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment (includes all current FDA-approved products)
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HIV PREVENTION EFFICACY

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HIV PREVENTION IMPACT

- HIV Viral Suppression
- HIV PrEP Uptake

IMPLEMENTATION SCIENCE

INTEGRATED STRATEGIES

- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level
- Culturally non-responsive services
- Structural barriers to social support

DETERMINANTS

CLINICAL OUTCOMES
Implementation Framework

**HIV PREVENTION EFFICACY**

**CLINICAL INTERVENTIONS**
- HIV Testing
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**HIV PREVENTION IMPACT**

**CLINICAL OUTCOMES**
- HIV Viral Suppression
- HIV PrEP Uptake

**IMPLEMENTATION SCIENCE**

**INTEGRATED STRATEGIES**
- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level
- Culturally non-responsive services
- Structural barriers to social support

**DETERMINANTS**

1. Intersectional Stigma
2. Community-level
3. Healthcare facility-Level
4. Culturally non-responsive services
5. Structural barriers to social support
Implementation Framework

HIV PREVENTION EFFICACY

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  (includes all current FDA-approved products)

IMPLEMENTATION SCIENCE

INTEGRATED STRATEGIES

- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level
- Culturally non-responsive services
- Structural barriers to social support

DETERMINANTS

HIV PREVENTION IMPACT

- HIV Viral Suppression
- HIV PrEP Uptake

CLINICAL OUTCOMES
CLINICAL OUTCOMES

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IMPLEMENTATION SCIENCE

INTEGRATED STRATEGIES

DETERMINANTS
- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level
- Culturally non-responsive services
- Structural barriers to social support

HIV PREVENTION IMPACT
- HIV Viral Suppression
- HIV PrEP Uptake
Implementation Framework

**HIV PREVENTION EFFICACY**

- HIV Testing
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**IMPLEMENTATION SCIENCE**

**INTEGRATED STRATEGIES**

- Intersectional Stigma
  - Community-level
  - Healthcare facility-Level
- Culturally non-responsive services
- Structural barriers to social support

**HIV PREVENTION IMPACT**

- HIV Viral Suppression
- HIV PrEP Uptake

**CLINICAL OUTCOMES**

- HIV Testing
- HIV Pre-Exposure Prophylaxis
- HIV Treatment
  (includes all current FDA-approved products)
Integrated Strategy

- Health Equity
- Virtual Peer Support
- Intersectional Stigma Reduction
- Social Media Influencers

- Increased PrEP Uptake & Adherence
- Increased HIV & STI Testing
- Increased ART Uptake & Adherence

- Reduction in HIV Incidence

- Increase in Black MSM who are protected from HIV infection (PrEP)
- Increase in Black MSM who are virally suppressed
Study Design

16 Communities in the Southern US < 8 matched pairs
Estimated Total Black MSM Population: 137,700 (range: 650 – 25,000 per community)

1:1 Community Randomization

Intervention Arm (8 communities)
- Baseline Cross-Sectional Assessment (N = 1600 Black MSM; status neutral; 100 men per community)
- Process Measures and Metrics of Implementation

Standard of Care Arm (8 communities)

HPTN 096 Integrated Strategy
(Health equity promotion, social media influencers, intersectional stigma reduction at healthcare facilities, virtual peer support)

Co-Primary Endpoints
1. Prevalence of PrEP use (biological samples, cross-sectional assessment)
2. Viral Suppression (CDC surveillance data)

1-year ramp-up (Phase 1)
3-year implementation

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Co-Primary Endpoints

1. Prevalence of PrEP use (biological samples, cross-sectional)
2. Viral Suppression (based on CDC surveillance data)
16 matched communities (~137,700 Black MSM)
8 intervention and 8 control

Back-up Communities
Community Engagement

- Community Listening Sessions
  - Georgia, South Carolina and Texas
- Community Strategy Group (CSG)
  - Guides community engagement activities
- Community Advisory Group (CAG)
  - 2 representatives from each study community
- Partnership with the Ending the Epidemic Committees in each study community
Partnerships and Engagement

- NIH (sponsor)
- CDC
- HRSA
- Black AIDS Institute
- Ending the HIV Epidemic Councils in each potential jurisdiction
  - Public health departments, CBOs, clinics, universities
- Community Strategy/Advisory Group
  - National Black Gay Men’s Advocacy Coalition
  - Black Gay Research Group
  - Association of Nurses in AIDS Care
  - National Black Nurses Association
- Gilead Sciences, Inc and ViiV Healthcare
HPTN 096: PrEP and ART

- Working with partners to have the most effective and safe PrEP options available
- Already in discussion with pharma companies
The study implementation will take place over the course of three years, after a one-year ramp-up period.

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Moving HPTN 096 Forward

• This is the right population.

• The time is now.

• HPTN 096 has a robust study design that can evaluate the impact of this integrated strategy on the uptake and use of biomedical interventions.
Acknowledgements

Study Co-Chairs: Chris Beyrer, MD and Bob Remien, PhD

Protocol Team:

NIH: Dale Burwen, David Burns, Michael Stirratt
CDC: Kevin Delaney, Irene Hall, Anna Satcher Johnson, Dawn Smith
HRSA: Keisha Bayne, Marcus Jackson, Angela Powell, Stacy Cohen, Shelita Merchant
Black AIDS Institute: Maximillian Boykin, Raniyah Copland, Elizabeth McGee, Rob Newells
HPTN Ethics Rep: Kathleen MacQueen
HPTN LOC: Theresa Gamble, Elizabeth Greene, Sherri Johnson, Ashley Mayo, Nicholas Hastings, Tanette Headen, Laura Long, Sam Alvarado, Kevin Bokoch, Gaby Salinas-Jimenez, Beth Farrell, Niru Sista
Community Reps: Marcus Bryan, Daniel Driffin, Melissa Turner
HPTN SDMC: James Hughes, Allison Meisner, Lynda Emel
HPTN LC: Susan Eshleman, Philip Sullivan
Pharma Reps: Christoph Carter, James Rooney
EHE Committee Reps: Melverta Bender, Krystle Cherry, Melvin Cauthen, Daniel Murdock
Additional Team Members: Bruce Agins, Marlon Bailey, Donte Boyd, Kendrick Clack, Donaldson Conserve, Patricia Coury-Doniger, Stephan Davis, Dustin Duncan, Errol Fields, Sheldon Fields, Charlotte Gaydos, Lisa Hightow-Weidman, Mandy Hill, Venton Hill-Jones, Christopher Hucks-Ortiz, Craig Hutchinson, Risha Irvin, Alex Keuroghlian, Tavell Kindall, Carmen Logie, Kenneth Mayer, Leisha McKinley-Beach, Leandro Mena, Ofole Mgbako, Kate Mitchell, Steve North, Gijvar Payne, Julie Pulerwitz, Justin Smith, Patrick Sullivan, DeAnne Turner, David Vlahov, Stephan Wallace, Darren Whitfield

Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619-15 (HPTN Leadership and Operations Center), UM1AI068617-15 (HPTN Statistical and Data Management Center), and UM1AI068613-15 (HPTN Laboratory Center).

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